

1/11

FIG. 1

GENERAL CONFIGURATION OF APPLICATION PREPARATION ASSISTING SYSTEM

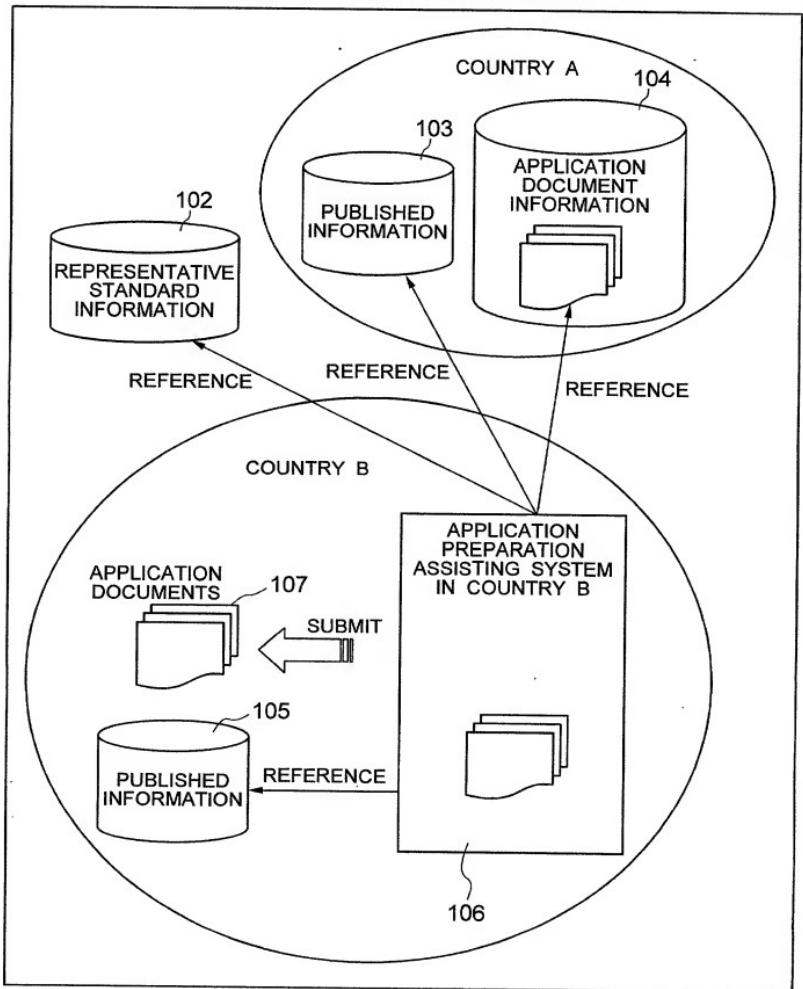
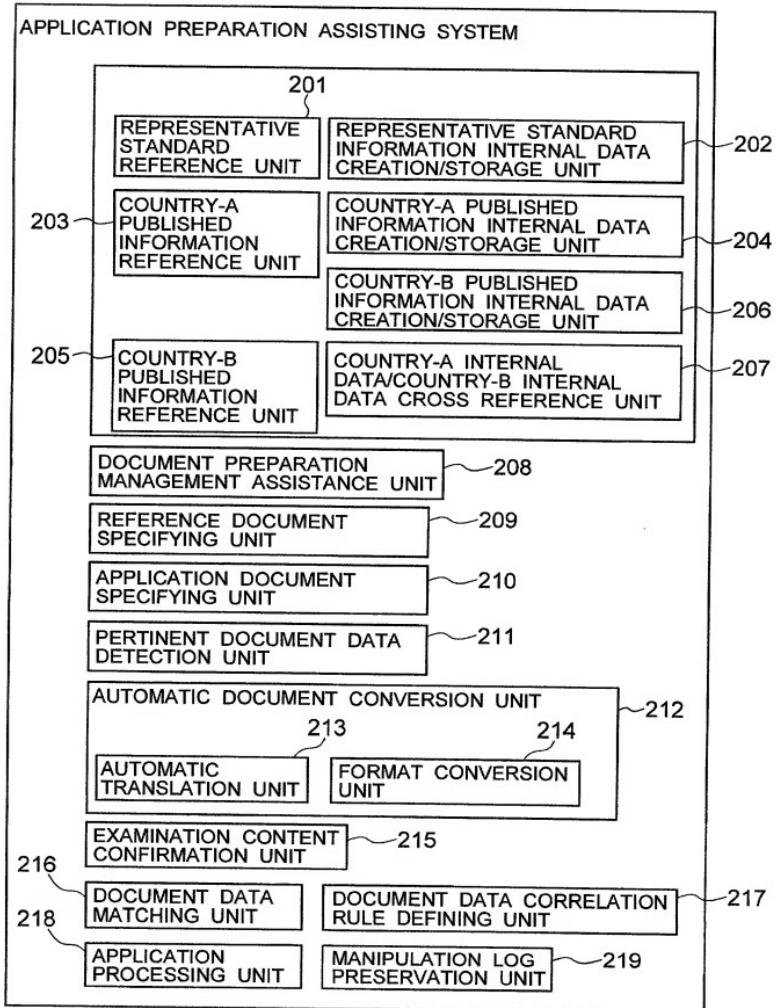


FIG. 2

CONFIGURATION OF APPLICATION PREPARATION
ASSISTING SYSTEM

10776554-0214902

FIG. 3

301

EXAMPLE OF REFERENCE DOCUMENT
SPECIFYING SCREEN

EXAMPLE OF REFERENCE DOCUMENT SPECIFYING SCREEN

 NEW PREPARATION SELECT AN APPLICATION FOR REFERENCE FROM THE FOLLOWINGS WHEN ALREADY PERMITTED.PERMITTING
COUNTRY


302

PRODUCT
NAME

303

OTHER SEARCH KEYWORD

304



DOCUMENTS FOUND BY SEARCH : ~~~305

✓ DOCUMENT No. XXX ON GASTROINTESTINAL DRUG ALPHA PERMITTED IN COUNTRY A ~~~306

OK

CANCEL

FIG. 4

EXAMPLE OF SCREEN FOR CONVERTING REFERENCE DOCUMENT TO DOCUMENT CONFORMING TO COUNTRY TO BE APPLIED 400

SCREEN FOR SPECIFYING CONVERSION TO COUNTRY OF INTEREST

SELECT COUNTRY TO WHICH NEW APPLICATION IS MADE, AND APPLICATION METHOD

COUNTRY TO BE APPLIED	COUNTRY B	401
USE	COMMERCIALLY AVAILABLE DRUG	402
SHAPE OF DRUG	CAPSULE	403
COMPONENT	WITHOUT ADJUSTMENT	404

405

WITHIN DOCUMENTS REQUIRED FOR APPLICATION,
DATA EXISTS CORRESPONDING TO DOCUMENTS
MARKED WITH SHADED SQUARE.
DO YOU SELECT AUTOMATIC CONVERSION ?

406

<input checked="" type="checkbox"/> APPLICATION 1	<input type="checkbox"/> APPLICATION 2	<input type="checkbox"/> APPLICATION 3
<input type="checkbox"/> APPLICATION 4	<input checked="" type="checkbox"/> APPLICATION 5	<input type="checkbox"/> APPLICATION 6
<input checked="" type="checkbox"/> APPLICATION 7	<input checked="" type="checkbox"/> APPLICATION 8	<input checked="" type="checkbox"/> APPLICATION 9

407

AUTOMATIC CONVERSION

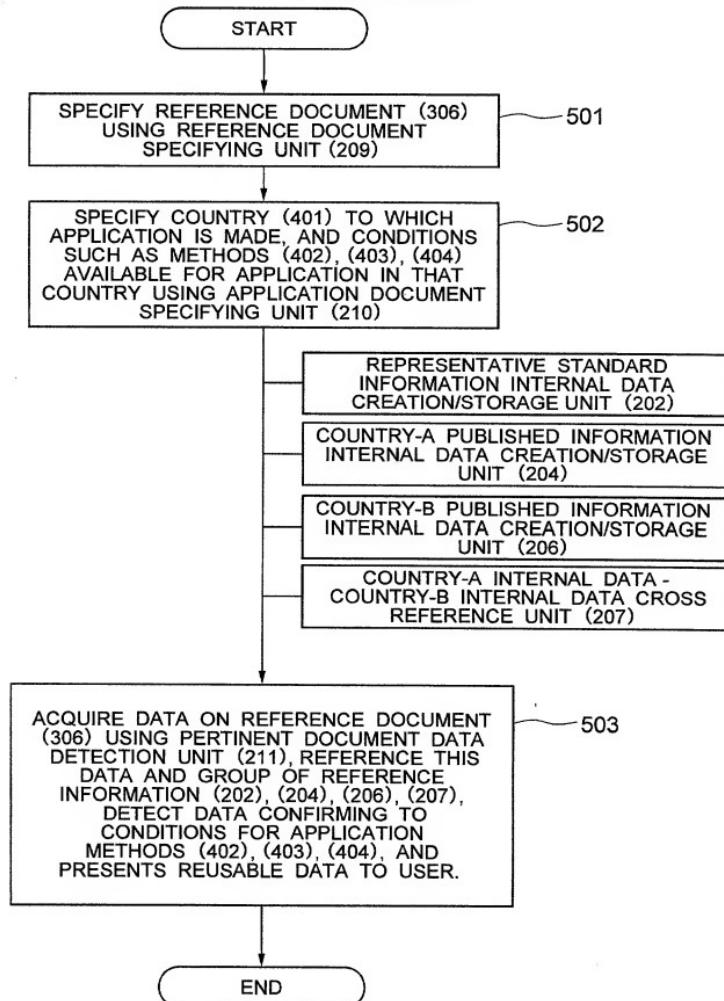
408

EDIT DOCUMENT

1001765554 - 0214902

FIG. 5

FLOW OF PROCESSING FOR CONVERTING REFERENCE DOCUMENT TO DOCUMENT CONFORMING TO COUNTRY TO WHICH APPLICATION IS MADE



10076554 - 021902

FIG. 6

EXAMPLE OF SCREEN WHEN AUTOMATIC CONVERSION IS INSTRUCTED

601

SCREEN FOR AUTOMATIC CONVERSION TO
APPLICATION IN COUNTRY B

AUTOMATICALLY CONVERT APPLICATION 1

AUTOMATIC TRANSLATION
(LANGUAGE IN COUNTRY A →
LANGUAGE IN COUNTRY B)
PROCESSING

602

FORMAT CONVERSION
PROCESSING

603



CONVERSION PROCESSING COMPLETED.
DO YOU WANT TO REGISTER APPLICATION
AS IT IS OR EDIT CONTENTS BEFORE
REGISTRATION ?

604

REGISTER

EDIT

605

10002654 - 001492

FIG. 7

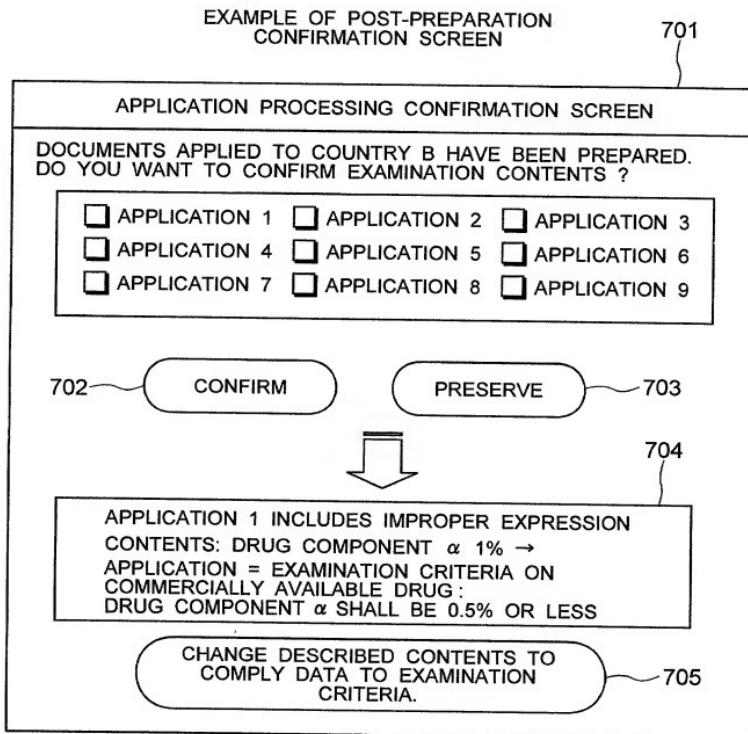


FIG. 8

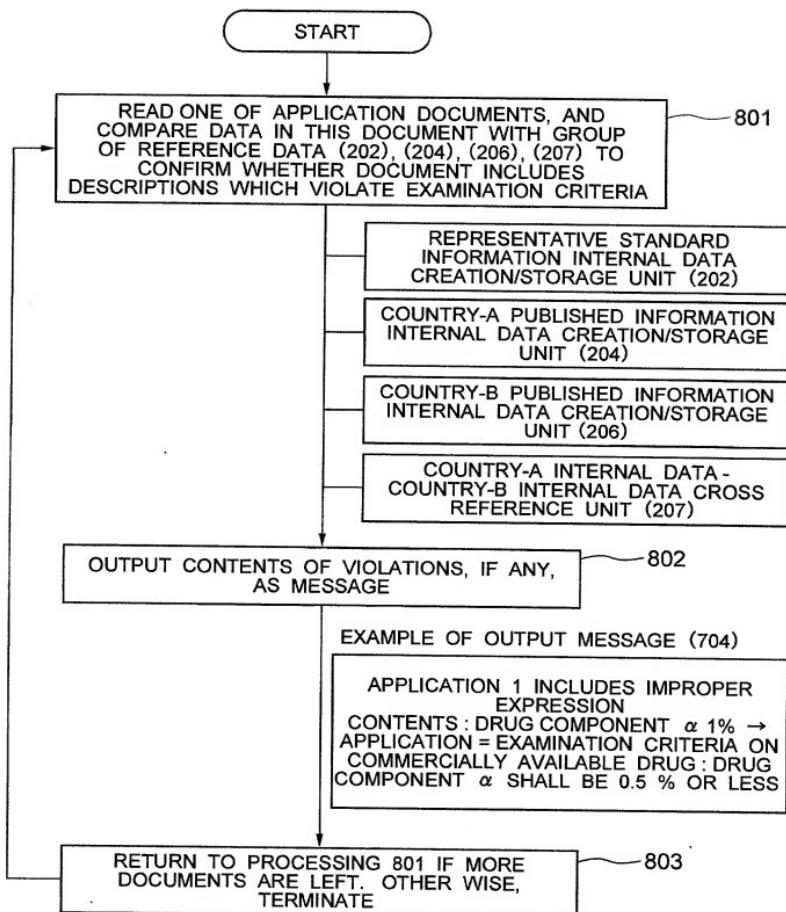
PROCESSING FLOW OF EXAMINATION
CONTENT CONFIRMATION UNIT (215)

FIG. 9

EXAMPLE OF DATA MATCHING SCREEN

901

DATA MATCHING SCREEN

APPLICATION 1 INCLUDES IMPROPER EXPRESSION
 CONTENTS : DRUG COMPONENT α 1% → EXAMINATION
 CRITERIA : DRUG COMPONENT α SHALL BE 0.5 % OR LESS

903
 FOR CHANGING
 COMPONENT, ASSOCIATED
 DATA = <CLINICAL DATA>
 MUST BE CHANGED.
 DO YOU WANT TO
 CHANGE ?

704

CHANGE

904

SELECT ASSOCIATED DATA
 FOR REPLACEMENT

- DRUG COMPONENT α 1%
- DRUG COMPONENT α 0.8%
- DRUG COMPONENT α 0.5%
- DRUG COMPONENT α 0.1%
- DRUG COMPONENT α 0.08 mg

REPLACE

<APPLICATION 1>
<COMPONENTS>
DRUG COMPONENT α 1 % ;
 β -CISTRON 0.025 % ;
 DRUG COMPONENT γ 0.08 mg
</COMPONENT>

<EFFECT>
 ANTIHFLLOGISTIC ACTION ON
 INNER WALLS OF STOMACH AND
 INTESTINE </EFFECT>

<DOSAGE>
 ADULTS (15 YEAR-OLD OR MORE) :
 TAKE ONE CAPSULE AFTER EVERY
 MEAL, CHILDREN (15-YEAR-OLD OR
 LESS) TAKE ONE CAPSULE A DAY
</DOSAGE>

<SIDE EFFECT>
 LOSS OF APPETITE </SIDE EFFECT>

<CLINICAL DATA>
 DATA ID - XXIILLLL
 COMPONENT : DRUG COMPONENT α
 1 % ; β -CISTRON 0.025 % ; DRUG
 COMPONENT γ 0.08 mg

</CLINICAL DATA>
</APPLICATION 1>

902

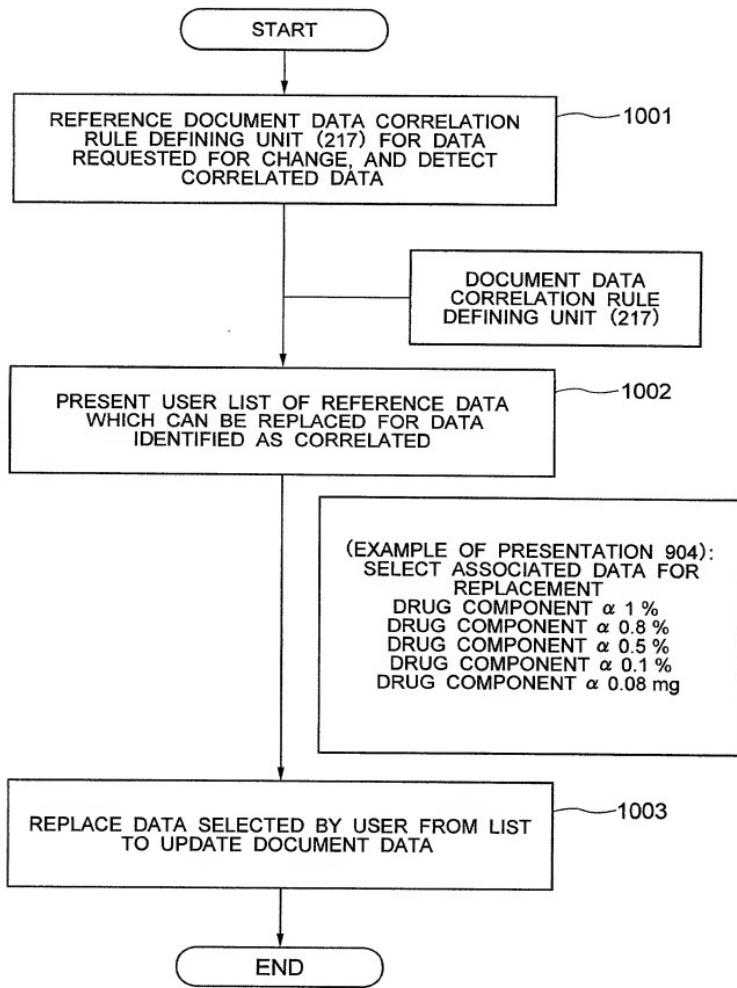
905

906

PRESERVE APPLICATION 1
AFTER REPLACEMENT

CANCEL

FIG. 10

PROCESSING FLOW IN DOCUMENT
MATCHING UNIT (216)

11/11

FIG. 11

EXAMPLE OF APPLICATION SUBMISSION SCREEN

1101

APPLICATION SUBMISSION SCREEN

EXAMINATION CONTENTS HAVE BEEN CONFIRMED FOR ALL DOCUMENTS. DO YOU WANT TO SUBMIT DOCUMENTS TO INTENDED COUNTRY ?

- | | | |
|--|--|--|
| <input type="checkbox"/> APPLICATION 1 | <input type="checkbox"/> APPLICATION 2 | <input type="checkbox"/> APPLICATION 3 |
| <input type="checkbox"/> APPLICATION 4 | <input type="checkbox"/> APPLICATION 5 | <input type="checkbox"/> APPLICATION 6 |
| <input type="checkbox"/> APPLICATION 7 | <input type="checkbox"/> APPLICATION 8 | <input type="checkbox"/> APPLICATION 9 |

SUBMIT

CANCEL



1102

SUBMISSION PROCESSING REQUEST HAS BEEN TRANSMITTED.

REQUEST TIME : XX:YY:ZZ IN STANDARD TIME OF COUNTRY B

(INTERNATIONAL STANDARD TIME = Date)

SUBMITTED DOCUMENTS AND SUBMISSION INFORMATION ARE PRESERVED BEFORE TERMINATION

STORAGE FILE : DOCUMENT ID = XXXIILLLLKKKK

PRODUCT NAME : GASTROINTESTINAL DRUG α

10076554-021802